



Our Docket No. 970663.CIP

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Re App : Geng Zhang, et al. : April 5, 2007
S. N. : 09/753,738 : Art Unit 3766
Filed : January 2, 2001 : Examiner Kennedy Schaetzle
For : AUTOCAPTURE PACING/SENSING
CONFIGURATION

APPEAL BRIEF FOR THE APPELLANTS

Mail Stop APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I. REAL PARTY IN INTEREST

The real party in interest is Cardiac Pacemakers, Inc.,
having offices at 4100 Hamline Avenue North, St. Paul, Minnesota
55112-5798; by virtue of Assignments from the inventors, each
recorded December 8, 1998, at Reel 010297, Frames 0848-0851, in
parent application.

II. RELATED APPEALS AND INTERFERENCES

There are no present appeals or interferences known to the
owner of the subject application, the owner's legal
representative, or the inventors which will directly affect or
be directly affected by or have a bearing on the Board of Patent

Appeals and Interferences in the pending appeal to the present knowledge of the undersigned.

An earlier appeal of related case S.N. 09/206,329 resulted in allowance on Appellants' Brief. That application issued as USPN 7,092,756.

III. STATUS OF THE CLAIMS

The present application was filed on January 2, 2001 as a Continuation-in-Part of the above-referenced application Serial No. 09/206,329, filed on December 8, 1998 and has undergone numerous Office Actions and amendments. The final Office Action from which this Appeal was taken was dated July 12, 2006. An After-Final Amendment was submitted on September 8, 2006 and an Advisory Action was issued September 29, 2006. The Advisory Action indicated that the after-final response would be entered for the purposes of appeal. On October 5, 2006, a Notice of Appeal was filed in the present Appeal in which claims 52, 53, 56-59 and 64-66 stand rejected. No claim has been allowed.

Thus, the present status of all claims is as follows:

1-51.	(Canceled)
52-53.	(Rejected)
54-55.	(Canceled)
56-59.	(Rejected)
60-63.	(Canceled)

64-66 (Rejected)

What Appellants believe to be a true copy of the claims presently under appeal appears in Appendix A attached to this Brief.

IV. STATUS OF AMENDMENTS

All amendments submitted in this application are believed to have been entered and are presently considered to be of record.

V. SUMMARY OF THE INVENTION

Cardiac pacers have enjoyed widespread use and popularity through time as a means for supplanting some or all of an abnormal heart's natural pacing functions. The various heart abnormalities remedied by pacemakers include total or partial heart block, arrhythmias, myocardial infarctions, congestive heart failure, congenital heart disorders, and various other rhythm disturbances within the heart. The general components of a cardiac pacemaker include an electronic pulse generator for generating stimulus pulses to the heart coupled to an electrode lead arrangement (unipolar or bipolar) positioned adjacent or within a preselected heart chamber for delivering pacing stimulus pulses.

Regardless of the type of cardiac pacemaker employed to restore the heart's natural rhythm (ie: ventricular pacing,

atrial pacing, or dual chamber pacing in both the atrium and ventricle), each type operates to stimulate excitable heart tissue cells adjacent to the electrode of the pacing lead employed with the pacemaker, which may or may not result in capture. Myocardial response to stimulation or "capture" is a function of the positive and negative charges found in each myocardial cell within the heart. The success of a pacing stimulus and depolarizing or "capturing" the selected chamber of the heart hinges on whether the current of the pacing stimulus as delivered to the myocardium exceeds a threshold value referred to as the capture threshold.

The ability of a pacemaker to detect capture threshold is desirable in that delivering stimulation pulses having energy far in excess of the patient's capture threshold is wasteful of the pacemaker's limited power supply. Thus, it is desirable that the amount of stimulation energy delivered to the myocardium is maintained at the lowest level that will reliably "capture" the heart. To accomplish this, a process known as "capture verification" must be performed wherein the pacemaker monitors to determine whether an evoked depolarization occurs in the preselected heart chamber following the delivery of each pacing stimulus pulse.

The detection of evoked depolarization or "capture verification" is rendered very difficult due to polarization voltages or "afterpotentials" which develop at heart tissue/electrode interface following the application of the stimulation pulses, thereby hampering the ability of the pacemaker to conduct automatic capture verification. Hence, there is a need for a cardiac pacing system that decrease and/or shortens the pacing afterpotentials.

The present invention provides a cardiac pacing system that attenuates, decreases and shortens pacing afterpotentials without significantly increasing the leading edge voltage pacing threshold and which may operate with a plurality of unipolar or bipolar leads without the necessity of a separate capture sensing lead and/or indifferent electrode. The pacing/sensing circuit of the invention may be utilized to determine whether a pacing stimulus directed to a selected atrium or ventricle evokes a response to the pacing stimulus. The preferred embodiment of the cardiac pacing system of the present invention includes an atrial pacing/sensing lead in a ventricle pacing/sensing lead electrically coupled to a cardiac pacemaker and includes leads for pacing in the atrium and/or ventricle, means for sensing an evoked response in the atrium and/or ventricle electrically coupled to the atrial and ventricle

leads, an afterpotential attenuation means for attenuating the afterpotential which results due to the application of a pacing stimulus to the heart.

As seen in the figures, the cardiac pacing system is one suitable for use with unipolar or bipolar atrial and ventricular pacing and sensing leads and includes at least an atrial lead 12 having atrial electrodes including an atrial tip electrode 28 and an atrial ring electrode 30 electronically coupled to the lead; and a ventricle lead 14 having ventricle electrodes including a ventricle tip electrode 32 and a ventricle ring electrode 33 electronically coupled to the lead. A pulse generator 20 for providing a pacing stimulus to at least one of an atrium or ventricle of a heart, the pacing means being electrically coupled to at least one of an atrial or ventricular lead. A sensing system for sensing a response evoked by the pacing stimulus in which the sensing device is electrically coupled to at least one of the atrial and ventricular leads and includes multiple independent blanking switches 58, 60 (Figure 7) corresponding to independent electrodes. An indifferent electrode 24 is provided and an electrically conductive can that contains the pacing and sensing systems 22, the indifferent electrode being situated on the can. An afterpotential attenuating system for attenuating afterpotentials (see Figure

8) is provided which is electrically coupled to the pacing means and includes a first coupling capacitor 94 for attenuating afterpotential operatively coupled to a second coupling capacitor 96 for blocking DC components. A switch 90 is provided for selectively coupling the second coupling capacitor in series with the first coupling capacitor so as to reduce the effective capacitance of the second coupling capacitor. The system has a combined reduced coupling capacitance of less than five microfarads, preferably 1-2 microfarads.

An important aspect of the invention lies in the fact that, with the combination of the present invention, the sensing system can selectively sense evoked responses between all combinations of any two of the electrodes. The versatility of this system is further demonstrated by the Figures 3-6 which illustrate further that the evoked response sense amplifier may be electrically coupled to sense evoked response wave forms resulting from either an atrial pacing stimulus or a ventricular pacing stimulus with any two-electrode sensing configuration. The figures illustrate alternate embodiments of this versatile concept.

More specifically, independent claims 65 and 66 are directed to a cardiac pacing system for use with unipolar or bipolar atrial and ventricular pacing and sensing leads which

includes the system for selectively sensing evoked responses between any combination of electrodes.

Independent claim 64 is directed to a method of automatically determining whether an electrical stimulus evokes a response in the heart when the stimulus is applied by a cardiac electrical stimulation system having atrial and ventricular leads, a pulse generator and a sensing circuit. The recited method includes providing stimulus and sensing capture in the form of a sensed response. The response can again be sensed between any pair of electrodes.

Each of the elements in the claims is believed to be clearly described and illustrated in the specification and drawings. Thus, an atrial lead is shown with reference to Figures 1-3, 5-6 as including a tip electrode 28 and a ring electrode 30. See also the text at page 9, line 16-page 11, line 24. A ventricular lead is also described in Figures 1-3, 5-6 and the text referenced just above. An electrical stimulation system is shown at 10 in Figure 1 and at 11 in Figure 2 and includes pulse generator 20 and pacing/sensing circuit 22. This element is further described with reference to the text at page 9, lines 16-31 and referenced at other places throughout the specification.

A sensing means is described in Figure 7 and in the text from page 17, line 24-page 18, line 26 and an afterpotential attenuation means is shown, for example, in Figure 8 and in the text on page 20 beginning at line 4 to line 31.

It is thus submitted that each of the elements of the independent claims is adequately described with reference to the specification and drawings.

VI. ISSUES ON APPEAL

The Advisory Action dated September 29, 2006 indicated that the rejections under § 102 and § 103 had been overcome by applicants' response dated September 8, 2006 and, therefore, the following issue remain:

1. Claims 52, 53, 56-59 and 64-66 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,169,921.

2. Claim 59 stands rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. More specifically, claim 59 is deemed to be vague because the applicants have not set forth all the various electrodes such that all recited combinations can be

selected. This is based on wording and base claim 65 in which alternative language is suggested by the Examiner.

3. Certain objections have been made to the lack of an antecedent for the reference to sensing *means* in claim 65.

In view of the foregoing, the issues remaining in this application involve rejection of claim 59 under 35 U.S.C. § 112, second paragraph, the non-statutory double patenting rejection based on USPN 6,169,921 against all claims and certain claim objections respecting an antecedent in claim 65.

VII. ARGUMENTS

A. Grouping of Claims

Appellants believe that each and every claim should stand or fall on its own merits and that the limitations of each should be considered separately. For example, many of the dependent claims require sensing between two specific electrodes selected as species from the concept that any two can be successfully used as evidenced by the independent claims.

B. The Cited Art

The only cited art remaining is in the form of U.S. Patent No. 6,169,921, which has been used to reject the claims under the judicially created doctrine of obviousness-type double patenting. If this rejection is maintained and the claims are deemed otherwise allowable, applicants stand ready and willing

to file the necessary Terminal Disclaimer regarding Patent No. 6,169,921.

C. Authorities and Arguments

Given that the applicants will agree to submit the necessary Terminal Disclaimer with respect to the rejection based on non-statutory double patenting, the remaining rejection under appeal is based on 35 USC § 112, second paragraph.

In applicants' response to the final rejection, claims 65 and 66 were amended to clarify the construction of the atrial and ventricular leads indicating that each contains "a plurality of electrodes including one of each type" and is now believed to better define the versatility of the sensing system. The term "sensing means" was changed to "sensing circuit" in indent (c), line 6, to agree with the antecedent term in line 1 of indent (c). In addition, claim 59 was amended to include a "superior vena cava coil electrode" and the sensing of the evoked response has been limited to "a group of combinations of electrodes" which are enumerated in the claim.

Accordingly, it is believed that the present language of claim 65 and claim 59 render claim 59 sufficiently definite that it does particularly point out and distinctly claim the subject matter of the applicants' invention.

CONCLUSION

Appellants believe that, in view of the above discussion, the present claims are, subject to the submission of a Terminal Disclaimer, in condition for allowance and it is respectfully requested that the final rejection of the Examiner be reversed and the claims be allowed.

Respectfully submitted,

NIKOLAI & MERSEREAU, P.A.

A handwritten signature in cursive script, appearing to read "C. G. Mersereau".

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Appeal Brief for the Appellants, Appendix A, B, C, all in triplicate, a Petition for a four-month extension of time, a check in the amount of \$1590.00, and a Transmittal Letter in application Serial No.09/753,738, filed January 2, 2001, of inventor(s) Geng Zhang et al, for "AUTOCAPTURE PACING/SENSING CONFIGURATION", are being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop APPEAL BRIEF - PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on April 5, 2007.



Barbara L. Davis

On Behalf of C. G. Mersereau

Date of Signature: April 5, 2007

APPENDIX A TO APPELLANTS' BRIEF

APPEALED CLAIMS

1-51(canceled).

52. An electrical cardiac stimulation system as in claim 65 wherein the electrical stimulus conducts electrically between an atrial tip electrode and the housing.

53. An electrical cardiac stimulation system as in claim 65 wherein the electrical stimulus conducts electrically between a ventricular tip electrode and the housing.

54-55(canceled).

56. An electrical cardiac stimulation system as in claim 66 wherein the signal associated with the evoked response is sensed between an atrial ring electrode and a ventricular electrode.

57. An electrical cardiac stimulation system as in claim 66 wherein the electrical stimulus conducts electrically between an atrial tip electrode and the housing.

58. An electrical cardiac stimulation system as in claim 66 wherein the electrical stimulus conducts electrically between a ventricular tip electrode and the housing.

59. An electrical cardiac stimulation system as in claim 65 further comprising a superior vena cava coil electrode and wherein the signal associated with the evoked response can be

selectively sensed between any one of a group of combinations of electrodes consisting of an atrial ring electrode to ventricular ring electrode, atrial ring electrode to can electrode, atrial ring electrode to ventricle coil electrode, atrial ring electrode to superior vena cava coil electrode, atrial tip electrode to ventricular coil electrode, atrial tip electrode to ventricular tip electrode, atrial tip electrode to atrial ring electrode, superior vena cava coil electrode to atrial tip electrode, superior vena cava coil electrode to ventricular coil electrode, superior vena cava coil electrode to ventricular tip electrode, ventricular tip electrode to ventricular coil electrode, superior vena cava coil electrode to ventricular ring electrode, and ventricular ring electrode to ventricular coil electrode.

60-63(canceled).

64. A method of automatically determining whether an electrical stimulus evokes a response in the heart when the stimulus is applied by a cardiac electrical stimulation system having atrial and ventricular leads, a pulse generator, and a sensing circuit, said method comprising the steps of:

- (a) providing an electrical stimulus to at least one of an atrium or ventricle of a heart;

- (b) attenuating afterpotential associated with said electrical stimulus;
- (c) selectively sensing an evoked response by the heart to the electrical stimulus, wherein a signal associated with an evoked response from the electrical stimulus is sensed between electrodes selected from the group, including atrial electrodes and ventricular electrodes of said leads wherein one of said electrodes selected is an atrial electrode and one of said electrodes is a ventricular electrode; and
- (d) wherein said atrial lead includes an atrial tip electrode and an atrial ring electrode, and said ventricular lead includes a ventricular tip electrode, a ventricular coil electrode, and a ventricular ring electrode.

65. An electrical cardiac stimulation system having an autocapture/stimulation/sensing configuration for use with atrial and ventricular leads, said electrical cardiac stimulation system including:

- (a) a combination of electrodes selected from a plurality of possible combinations of electrodes, at least one electrode of each said combination being selected from groups consisting of a plurality of atrial electrodes

and a plurality of ventricular electrodes and at least one electrode of said combination optionally being selected from groups consisting of can electrodes and vena cava electrodes;

- (b) a stimulation system enclosed in a housing, said stimulation system being electrically coupled to each said atrial electrode and each said ventricular electrode for providing an electrical stimulus to at least one of an atrium or ventricle of a heart;
- (c) a sensing circuit that senses an evoked response by the heart to the electrical stimulus, wherein a signal associated with an evoked response from the electrical stimulus is sensed between at least two of said electrodes of said combination and when said sensing circuit is adapted to selectively sense evoked responses between all combinations of any two of said electrodes;
- (d) an afterpotential attenuation device for attenuating afterpotentials which result due to the application of the pacing stimulus to the heart by said electrical stimulation system, said afterpotential attenuation device being electrically coupled to said stimulation system;

- (e) an atrial lead including a plurality of atrial electrodes, said atrial electrodes including an atrial tip electrode and an atrial ring electrode; and
- (f) a ventricular lead including a plurality of ventricular electrodes including a ventricular tip electrode, a ventricular coil electrode, and a ventricular ring electrode.

66. An electrical cardiac stimulation system having an autocapture stimulation/sensing configuration for use with atrial and ventricular leads, said electrical cardiac stimulation system including:

- (a) a combination of electrodes selected from a plurality of possible combinations of electrodes, at least one electrode of each said combination being selected from groups consisting of a plurality of atrial electrodes and a plurality of ventricular electrodes and at least one electrode of said combination optionally being selected from groups consisting of can electrodes and vena cava electrodes;
- (b) a stimulation means enclosed in a housing, said stimulation means being electrically coupled to each said atrial electrode and each said ventricular

- electrode for providing an electrical stimulus to at least one of an atrium or ventricle of a heart;
- (c) a sensing means that senses an evoked response by the heart to the electrical stimulus, wherein a signal associated with an evoked response from the electrical stimulus is sensed between at least two of said electrodes of said combination and when said sensing means is adapted to selectively sense evoked responses between all combinations of any two of said electrodes;
 - (d) an afterpotential attenuation means for attenuating afterpotentials which result due to the application of the pacing stimulus to the heart by said electrical stimulation means, said afterpotential attenuation means being electrically coupled to said stimulation means;
 - (e) an atrial lead including a plurality of atrial electrodes including an atrial tip electrode and an atrial ring electrode; and
 - (f) a ventricular lead including a plurality of ventricular electrodes including a ventricular tip electrode, a ventricular coil electrode, and a ventricular ring electrode.

APPENDIX B TO APPELLANTS' BRIEF

EVIDENCE APPENDIX

None

APPENDIX C TO APPELLANTS' BRIEF

RELATED PROCEEDINGS APPENDIX

None